Claims

1. A method of determining an analyte in a sample comprising the steps of:

a) contacting the sample with a specified amount of a receptor which binds specifically to the analyte to form an analyte/receptor complex, said specified amount of receptor being in excess of that required to bind all analyte in the sample,

b) isolating on a solid phase a specified fraction of the amount of receptor contacted with the analyte, including analyte/receptor complex and unreacted receptor,

c) detecting the amount of analyte/receptor complex in said isolated specified fraction, and

d) from the detected amount analyte/receptor complex, determining the concentration of analyte in the sample.

2. The method according to claim 1 in which the sample has a high concentration.

3. The method according to claim 1 or claim 2 in which the sample is undiluted.

4. The method according to claims 1 to 3, wherein isolating said specified fraction of the amount of receptor contacted with the sample on the solid phase comprises providing a solid phase having binding sites for the receptor, and after contacting the sample, or an aliquot thereof, with a liquid phase containing the receptor, binding said specified fraction of receptor to the solid phase.

5. The method according to claim 4, wherein the whole amount of receptor has reactivity towards said binding sites on the solid phase, and the receptor-binding

capacity of the solid phase is less than the solid-phase-binding capacity of receptor contacted with the sample.

6. The method according to claim 4, wherein only a specified fraction of the amount of receptor contacted with the sample has reactivity towards said binding sites on the solid phase.

7. The method according to claims 1 to 3, wherein isolating said specified fraction of the amount of receptor on the solid phase comprises contacting the sample with a specified amount of receptor, a specified fraction of which amount is immobilized to said solid phase and the remaining amount of receptor being in a liquid phase.

8. The method according to any one of claims 1 to 6, wherein the receptor comprises a first part that binds specifically to the analyte, and a second part that binds to the solid phase.

9. The method according to claim 8, wherein the solid phase binding part of the receptor comprises one member of a specific binding pair, and the other member of the binding pair is immobilized to the solid phase.

10. The method according to any one the preceding of claims, wherein in step c) the analyte/receptor complex is detected by a labelled detection reagent which binds specifically to the analyte.

11. The method according to any one of the preceding claims, wherein the ratio between said isolated fraction of the amount of active analyte-binding receptor and the total amount of active analyte-binding receptor contacted with the sample is in the range

of from about 1:2 to about 1:1000, preferably from about 1:5 to about 1:100, particularly no more than about 1:20.

12. The method according to any one of the preceding claims, wherein said solid phase binding sites for the receptor are immobilized in a reaction zone of a flow matrix, preferably a lateral flow matrix, such as a membrane strip.

13. The method according to any one of the preceding claims, wherein the receptor is an antibody or an immunoactive fragment thereof.

14. The method according to any one of the preceding claims, wherein the detection reagent is an antibody or an immunoactive fragment thereof.

15. The method according to any one of the preceding claims, wherein the detection reagent is labelled by a fluorophore or a chromophore.

16. The method according to any one of the preceding claims, wherein the specific binding pair is biotin-avidin or biotin-streptavidin.

17. The method according to any one of the preceding claims, wherein the sample is an undiluted serum sample.

18. The method according to any one of claims 1 to 16, wherein the sample is an undiluted whole blood sample.